CLAIMS

1. A method for screening, diagnosis or prognosis of kidney response in a subject, for determining the stage or severity of kidney response in a subject, for identifying a subject at risk of developing kidney response, or for monitoring the effect of therapy administered to a subject having kidney response, said method comprising:

(a) analyzing a test sample of tissue or body fluid from the subject by two dimensional electrophoresis to generate a two-dimensional array of features, said array comprising one or more Kidney Response-Associated Features (KRF)s selected from the group consisting of KRF-1, KRF-2, KRF-3, KRF-4, KRF-5, KRF-6, KRF-7, KRF-8, KRF-9, KRF-10, KRF-11, KRF-12, KRF-13, KRF-14, KRF-15, KRF-16, KRF-17, KRF-18, KRF-19, KRF-20, KRF-21, KRF-22, KRF-23, KRF-24, KRF-25, KRF-26, KRF-27, KRF-28, KRF-29, KRF-30, KRF-31, KRF-32, KRF-33, KRF-34, KRF-35, KRF-36, KRF-37, KRF-38, KRF-39, KRF-40, KRF-41, KRF-42, KRF-43, KRF-44, KRF-45, KRF-46, KRF-47, KRF-48, KRF-49, KRF-50, KRF-51, KRF-52, KRF-53, KRF-54, KRF-55, KRF-56, KRF-57, KRF-58, KRF-59, KRF-60, KRF-61, KRF-62, KRF-63, KRF-64, KRF-65, KRF-66, KRF-67, KRF-68, KRF-69, KRF-70, KRF-71, KRF-72, KRF-73, KRF-74, KRF-75, KRF-76, KRF-77, KRF-78, KRF-79, KRF-80, KRF-81, KRF-82, KRF-83, KRF-84, KRF-85, KRF-86, KRF-87, KRF-88, KRF-89, KRF-90, KRF-91, KRF-92, KRF-93, KRF-94, KRF-95, KRF-96, KRF-97, KRF-98, KRF-99, KRF-100, KRF-101, KRF-102, KRF-103, KRF-104, KRF-105, KRF-106, KRF-107, KRF-108, KRF-109, KRF-110, KRF-111, KRF-112, KRF-113, KRF-114, KRF-115, KRF-116, KRF-117, KRF-118, KRF-119, KRF-120, KRF-121, KRF-122, KRF-123, KRF-124, KRF-125, KRF-126, KRF-127, KRF-128, KRF-129, KRF-130, KRF-131, KRF-132, KRF-133, KRF-134, KRF-135, KRF-136, KRF-137, KRF-138, KRF-139, KRF-140, KRF-141, KRF-142, KRF-143, KRF-144, KRF-145, KRF-146, KRF-147, KRF-148, KRF-149, KRF-150, KRF-151, KRF-152, KRF-153, KRF-154, KRF-155, KRF-156, KRF-157, KRF-158, KRF-159, KRF-160, KRF-161, KRF-162, KRF-163, KRF-164, KRF-165, KRF-166, KRF-167, KRF-168, KRF-169, KRF-170, KRF-171, KRF-172, KRF-173, KRF-174, KRF-175, KRF-176, KRF-177, KRF-178, KRF-179, KRF-180, KRF-181, KRF-182, KRF-183, KRF-184, KRF-185, KRF-186, KRF-187, KRF-188, KRF-189, KRF-190, KRF-191, KRF-192, KRF-193, KRF-194, KRF-195, KRF-196, KRF-197, KRF-198, KRF-199, KRF-200, KRF-201, KRF-202, KRF-203, KRF-204, KRF-205, KRF-206, KRF-207, KRF-208, KRF-209, KRF-210, KRF-211, KRF-212, KRF-213, KRF-214, KRF-215, KRF-216, KRF-217, KRF-218, KRF-219, KRF-220, KRF-221, KRF-222, KRF-223, KRF-224, KRF-225, KRF-226, KRF-227, KRF-228, KRF-229, KRF-230, KRF-231, KRF-232, KRF-233, KRF-234, KRF-235, KRF-236, KRF-237, KRF-238, KRF-239, KRF-240, KRF-241, KRF-242, KRF-243, KRF-244, KRF-245, KRF-246, KRF-247, KRF-248, KRF-249, KRF-250, KRF-251, KRF-252, KRF-253, KRF-254, KRF-255, KRF-256, KRF-257, KRF-258, KRF-259, KRF-260, KRF-261, KRF-262, KRF-263, KRF-264, KRF-265, KRF-266, KRF-267, KRF-268, KRF-269, KRF-270, KRF-271, KRF-272, KRF-273, KRF-274, KRF-275, KRF-276, KRF-277, KRF-278, KRF-279, KRF-280, KRF-281, KRF-282, KRF-283, KRF-284, KRF-285, KRF-286, KRF-287, KRF-288, KRF-289, KRF-290, KRF-291, KRF-292, KRF-293, KRF-294, KRF-295, KRF-296, KRF-297, KRF-298, KRF-299, KRF-300, KRF-301, KRF-302, KRF-303, KRF-304, KRF-305, KRF-306, KRF-307, KRF-308, KRF-309, KRF-310, KRF-311, KRF-312, KRF-313, KRF-314,

KRF-315, KRF-316, KRF-317, KRF-318, KRF-319, KRF-320, KRF-321, KRF-322, KRF-323, KRF-324, KRF-325, KRF-326, KRF-327, KRF-328, KRF-329, KRF-330, KRF-331, KRF-332, KRF-333, KRF-334, KRF-335, KRF-336, KRF-337, KRF-338, KRF-339, KRF-340, KRF-341, KRF-342, KRF-343, KRF-344, KRF-345, KRF-346, KRF-347, KRF-348, KRF-349, KRF-350, KRF-351 and KRF-352,
whose relative abundance correlates with the presence, absence, stage or severity of kidney response or predicts the onset or course of kidney response; and

(b) comparing the abundance of each selected feature in the test sample with the abundance of that chosen feature in tissue or body fluid from one or more subjects free from kidney response, or with a previously determined reference range for that feature in subjects free from kidney response, or with the abundance at least one Expression Reference Feature (ERF) in the test sample.

2. The method according to claim 1, wherein said method is for determining the ability of drug candidates to induce an unwanted kidney response.

3. The method of claim 1, wherein the tissue is kidney tissue and the KRFs are selected from the group consisting of KRF-1, KRF-2, KRF-3, KRF-4, KRF-5, KRF-6, KRF-7, KRF-8, KRF-9, KRF-10, KRF-11, KRF-12, KRF-13, KRF-14, KRF-15, KRF-16, KRF-17, KRF-18, KRF-19, KRF-20, KRF-21, KRF-22, KRF-23, KRF-24, KRF-25, KRF-26, KRF-27, KRF-28, KRF-29, KRF-30, KRF-31, KRF-32, KRF-33, KRF-34, KRF-35, KRF-36, KRF-37, KRF-38, KRF-39, KRF-40, KRF-41, KRF-42, KRF-43, KRF-44, KRF-45, KRF-46, KRF-47, KRF-48, KRF-49, KRF-50, KRF-51, KRF-52, KRF-53, KRF-54, KRF-55, KRF-56, KRF-57, KRF-58, KRF-59, KRF-60, KRF-61, KRF-62, KRF-63, KRF-64, KRF-65, KRF-66, KRF-67, KRF-68, KRF-69, KRF-70, KRF-71, KRF-72, KRF-73, KRF-74, KRF-75, KRF-76, KRF-77, KRF-78, KRF-79, KRF-80, KRF-81, KRF-82, KRF-83, KRF-84, KRF-85, KRF-86, KRF-87, KRF-88, KRF-89, KRF-90, KRF-91, KRF-92, KRF-93, KRF-94, KRF-95, KRF-96, KRF-97, KRF-98, KRF-99, KRF-100, KRF-101, KRF-102, KRF-103, KRF-104, KRF-105, KRF-106, KRF-107, KRF-108, KRF-109, KRF-110, KRF-111, KRF-112, KRF-113, KRF-114, KRF-115, KRF-116, KRF-117, KRF-118, KRF-119, KRF-120, KRF-121, KRF-122, KRF-123, KRF-124, KRF-125, KRF-126, KRF-127, KRF-128, KRF-129, KRF-130, KRF-131, KRF-132, KRF-133, KRF-134, KRF-135, KRF-136, KRF-137, KRF-138, KRF-139, KRF-140, KRF-141, KRF-142, KRF-143, KRF-144, KRF-145, KRF-146, KRF-147, KRF-148, KRF-149, KRF-150, KRF-151, KRF-152, KRF-153, KRF-154, KRF-155, KRF-156, KRF-157, KRF-158, KRF-159, KRF-160, KRF-161, KRF-162, KRF-163, KRF-164, KRF-165, KRF-166, KRF-167, KRF-168, KRF-169, KRF-170, KRF-171, KRF-172, KRF-173, KRF-174, KRF-175, KRF-176, KRF-177, KRF-178, KRF-179, KRF-180, KRF-181, KRF-182, KRF-183, KRF-184, KRF-185, KRF-186, KRF-187, KRF-188, KRF-189, KRF-190, KRF-191, KRF-192, KRF-193, KRF-194, KRF-195, KRF-196, KRF-197, KRF-198, KRF-199, KRF-200, KRF-201, KRF-202, KRF-203, KRF-204, KRF-205, KRF-206, KRF-207, KRF-208, KRF-209, KRF-210, KRF-211, KRF-212, KRF-213, KRF-214, KRF-215, KRF-216, KRF-217, KRF-218, KRF-219, KRF-220, KRF-221, KRF-222, KRF-223, KRF-224, KRF-225, KRF-226, KRF-227, KRF-228, KRF-229, KRF-230, KRF-231, KRF-232, KRF-233, KRF-234, KRF-235, KRF-236, KRF-237, KRF-238, KRF-239,

KRF-240, KRF-241, KRF-242, KRF-243, KRF-244, KRF-245, KRF-246, KRF-247, KRF-248, KRF-249, KRF-250, KRF-251, KRF-252, KRF-253, KRF-254, KRF-255, KRF-256, KRF-257, KRF-258, KRF-259, KRF-260, KRF-261, KRF-262, KRF-263, KRF-264, KRF-265, KRF-266, KRF-267, KRF-268, KRF-269, KRF-270, KRF-271, KRF-272, KRF-273, KRF-274, KRF-275, KRF-276, KRF-277, KRF-278, KRF-279, KRF-280, KRF-281, KRF-282, KRF-283, KRF-284, KRF-285, KRF-286, KRF-287, KRF-288 and KRF-289.

4. The method according to claim 3, wherein said method is for determining the ability of drug candidates to induce an unwanted kidney response.

5. The method of claim 1, wherein the body fluid is blood or serum or plasma and the KRFs are selected from the group consisting of KRF-290, KRF-291, KRF-292, KRF-293, KRF-294, KRF-295, KRF-296, KRF-297, KRF-298, KRF-299, KRF-300, KRF-301, KRF-302, KRF-303, KRF-304, KRF-305, KRF-306, KRF-307, KRF-308, KRF-309, KRF-310, KRF-311, KRF-312, KRF-313, KRF-314, KRF-315, KRF-316, KRF-317, KRF-318, KRF-319, KRF-320, KRF-321, KRF-322, KRF-323, KRF-324, KRF-325, KRF-326, KRF-327, KRF-328, KRF-329, KRF-330, KRF-331, KRF-332, KRF-333, KRF-334, KRF-335, KRF-336, KRF-337, KRF-338, KRF-339, KRF-340, KRF-341, KRF-342, KRF-343, KRF-344, KRF-345, KRF-346, KRF-347, KRF-348, KRF-349, KRF-350, KRF-351 and KRF-352.

6. The method according to claim 5, wherein said method is for determining the ability of drug candidates to induce an unwanted kidney response.

7. A method for screening, diagnosis or prognosis of kidney response in a subject, for determining the stage or severity of kidney response in a subject, for identifying a subject at risk of developing kidney response, or for monitoring the effect of therapy administered to a subject having kidney response, said method comprising:

(a) quantitatively detecting, in a sample of kidney tissue from the subject, at least one Kidney Response-Associated Protein Isoform (KRPI) selected from the group consisting of: KRPI-2, KRPI-8, KRPI-11, KRPI-13, KRPI-14, KRPI-15, KRPI-16, KRPI-19, KRPI-21, KRPI-23, KRPI-27, KRPI-28, KRPI-35, KRPI-40, KRPI-41, KRPI-42, KRPI-43, KRPI-45.1, KRPI-45.2, KRPI-57, KRPI-59, KRPI-60, KRPI-63, KRPI-70, KRPI-72, KRPI-73, KRPI-76, KRPI-84, KRPI-85, KRPI-86, KRPI-88, KRPI-90, KRPI-91, KRPI-98, KRPI-101, KRPI-104, KRPI-105, KRPI-113, KRPI-122, KRPI-123, KRPI-128, KRPI-131, KRPI-132, KRPI-134, KRPI-138, KRPI-139, KRPI-142, KRPI-143, KRPI-144, KRPI-149, KRPI-152, KRPI-153, KRPI-158, KRPI-159, KRPI-168, KRPI-170, KRPI-178, KRPI-179, KRPI-183, KRPI-184, KRPI-185, KRPI-186, KRPI-188, KRPI-189.1, KRPI-189.2, KRPI-192, KRPI-196, KRPI-202, KRPI-206, KRPI-208, KRPI-210, KRPI-219, KRPI-222, KRPI-229, KRPI-232, KRPI-235.1, KRPI-235.2, KRPI-236, KRPI-237, KRPI-240, KRPI-245, KRPI-247, KRPI-249, KRPI-250, KRPI-252, KRPI-253,

KRPI-256, KRPI-257, KRPI-263, KRPI-267, KRPI-273, KRPI-278, KRPI-280, KRPI-282, KRPI-285 and KRPI-286, and

(b) comparing the level or amount of said isoform or isoforms detected in step (a) with a control.

8. The method according to claim 7, wherein the step of quantitatively detecting comprises testing at least one aliquot of the sample, said step of testing comprising:

contacting the aliquot with an antibody that is immunospecific for a preselected KRPI;

(a) quantitatively measuring any binding that has occurred between the antibody and at least one species in the aliquot; and

(b) comparing the results of step (b) to a control.

9. The method according to claim 7, wherein said method is for determining the ability of drug candidates to induce an unwanted kidney response.

10. The method according to claim 7, wherein the subject is a rat.

11. A method for screening, diagnosis or prognosis of kidney response in a subject, for determining the stage or severity of kidney response in a subject, for identifying a subject at risk of developing kidney response, or for monitoring the effect of therapy administered to a subject having kidney response, said method comprising:

(a) quantitatively detecting, in a sample of blood, serum or plasma from the subject, at least one Kidney Response-Associated Protein Isoform (KRPI) selected from the group consisiting of: KRPI-313, KRPI-314.1, KRPI-314.2, KRPI-327.1, KRPI-327.2 and KRPI-339, and

(b) comparing the level or amount of said isoform or isoforms detected in step (a) with a control.

12. The method according to claim 11, wherein the step of quantitatively detecting comprises testing at least one aliquot of the sample, said step of testing comprising:

(a) contacting the aliquot with an antibody that is immunospecific for a preselected KRPI;

(b) quantitatively measuring any binding that has occurred between the antibody and at least one species in the aliquot; and

(c) comparing the results of step (b) to a control.

13. The method according to claim 11, wherein said method is for determining the ability of drug candidates to induce an unwanted kidney response.

14. The method according to claim 11, wherein the subject is a rat.

15. A method for screening, diagnosis or prognosis of kidney response in a subject, for determining the stage or severity of kidney response in a subject, for identifying a subject at risk of developing kidney response, or for monitoring the effect of therapy administered to a subject having kidney response, said method comprising:

(a) contacting at least one oligonucleotide probe comprising 10 or more consecutive nucleotides complementary to a nucleotide sequence encoding a KRPI selected from the group consisting of KRPI-2, KRPI-8, KRPI-11, KRPI-13, KRPI-14, KRPI-15, KRPI-16, KRPI-19, KRPI-21, KRPI-23, KRPI-27, KRPI-28, KRPI-35, KRPI-40, KRPI-41, KRPI-42, KRPI-43, KRPI-45.1, KRPI-45.2, KRPI-57, KRPI-59, KRPI-60, KRPI-63, KRPI-70, KRPI-72, KRPI-73, KRPI-76, KRPI-84, KRPI-85, KRPI-86, KRPI-88, KRPI-90, KRPI-91, KRPI-98, KRPI-101, KRPI-104, KRPI-105, KRPI-113, KRPI-122, KRPI-123, KRPI-128, KRPI-131, KRPI-132, KRPI-134, KRPI-138, KRPI-139, KRPI-142, KRPI-143, KRPI-144, KRPI-149, KRPI-152, KRPI-153, KRPI-158, KRPI-159, KRPI-168, KRPI-170, KRPI-178, KRPI-179, KRPI-183, KRPI-184, KRPI-185, KRPI-186, KRPI-188, KRPI-189.1, KRPI-189.2, KRPI-192, KRPI-196, KRPI-202, KRPI-206, KRPI-208, KRPI-210, KRPI-219, KRPI-222, KRPI-229, KRPI-232, KRPI-235.1, KRPI-235.2, KRPI-236, KRPI-237, KRPI-240, KRPI-245, KRPI-247, KRPI-249, KRPI-250, KRPI-252, KRPI-253, KRPI-256, KRPI-257, KRPI-263, KRPI-267, KRPI-273, KRPI-278, KRPI-280, KRPI-282, KRPI-285, KRPI-286, KRPI-313, KRPI-314.1, KRPI-314.2, KRPI-327.1, KRPI-327.2 and KRPI-339 and orthologs thereof, with an RNA obtained from a biological sample from the subject or with cDNA copied from the RNA wherein said contacting occurs under conditions that permit hybridization of the probe to the nucleotide sequence if present;

(b) detecting hybridization, if any, between the probe and the nucleotide sequence; and

(c) comparing the hybridization, if any, detected in step (b) with the hybridization detected in a control sample, or with a previously determined reference range.

16. The method of claim 15, wherein step (a) includes the step of hybridizing the nucleotide sequence to a DNA array, wherein one or more members of the array are the probes complementary to a plurality of nucleotide sequences encoding distinct KRPIs.

17. The method according to claim 15, wherein said method is for determining the ability of drug candidates to induce an unwanted kidney response.

18. A diagnostic kit adapted for use in the method of claim 7 comprising a capture reagent capable of capturing a KRPI may additionally optionally comprise one or more of the following:

(1) instructions for using the capture reagent;

(2) a labeled binding partner to the capture reagent;

(3) a solid phase upon which the capture reagent is immobilized; and

(4) a label or insert indicating regulatory approval for use, or any combination thereof.

19. A diagnostic kit adapted for use in the method of claim 11 comprising a capture reagent capable of capturing a KRPI may additionally optionally comprise one or more of the following:

(1) instructions for using the capture reagent;

(2) a labeled binding partner to the capture reagent;

(3) a solid phase upon which the capture reagent is immobilized; and

(4) a label or insert indicating regulatory approval for use, or any combination thereof.